



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,879	10/16/2003	Anthony Winston	49000	7393

7590 12/16/2005
Stephen B. Shear
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543-5297

EXAMINER

KRASS, FREDERICK F

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/686,879	Applicant(s) WINSTON ET AL.	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/20/04</u> . | 6) <input type="checkbox"/> Other: ____. |

Enablement Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 5-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for dentifrices comprising “anionic components reactive with sodium and water to form hydrated crystals”, and which are selected from the group consisting of orthophosphates, pyrophosphates, tripolyphosphates, metaphosphates, borates, thiosulfates, and glycerophosphates, does not reasonably provide enablement for dentifrices comprising such “anionic components reactive with sodium and water to form hydrated crystals” generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,

Art Unit: 1614

- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth infra.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

While the relative skill of those in the art is high (that of a PHD, Pharm. D., or D.D.S), this is outweighed by the unpredictable nature of the invention. The prior art recognizes that crystal formation in toothpastes is complex, and cannot be extrapolated from simple models because complete dentrifications are very complicated systems: see USP 5,599,526 at the passage bridging cols. 1 and 2, and at col. 2, lines 30-42. Thus, the ability of any given "anionic component" to form crystals by reaction with sodium bicarbonate in a given dentifrice would not be expected to be consistently predictable in *a priori* manner.

2. The breadth of the claims

The rejected claims are extremely broad and inclusive of any and all possible “anionic components” capable of forming crystals by reaction with sodium bicarbonate within a dentifrice formulation.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no guidance for selecting any particular “anionic components” reactive with sodium and water to form hydrated crystals within dentifrice formulations, other than orthophosphates, pyrophosphates, tripolyphosphates, metaphosphates, borates, thiosulfates, and glycerophosphates as disclosed by the instant specification at p. 7, lines 10-14, and used in the working examples.

4. The quantity of experimentation necessary

Applicant fails to provide information allowing the skilled artisan to ascertain which particular “anionic components”, other than those specifically enumerated by name, can reasonably be expected to react with sodium and water to form hydrated crystals in dentifrice formulations. In the instant case, only a limited number of species are exemplified. Crystal formation in dentifrices is generally unpredictable, requiring individual formulations to be empirically assessed. Given the sheer number and diversity of candidate species and the recognized unpredictability of this art, one would

Art Unit: 1614

have to mount a substantial research campaign to determine which 'anionic components" other than orthophosphates, pyrophosphates, tripolyphosphates, metaphosphates, borates, thiosulfates, and glycerophosphates within the scope of the instant claims would exhibit the required reactivity with sodium bicarbonate and water produce hydrated crystals within dentifrices. Accordingly, applicant has failed to provide information sufficient to practice the claimed invention absent resorting to undue experimentation.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claim 1, fourth and fifth lines, the recitation "or other dissolved species" is confusing, since none of the species preceding that recitation (humectant, thickener or abrasive) is generally a "dissolved species" in the dentifrice art.

2) Claim 1, last two lines, the term "about" is deemed indefinite as used in connection with the value "0.60" to define the claimed "water activity."

Art Unit: 1614

The term “about” permits some tolerance, and is normally definite. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946), where “at least about 10%” was held to be anticipated by a teaching of a content “not to exceed about 8%.” Where close prior art exists, however, the normally definite term “about” can become indefinite, with Applicant bearing the burden of establishing that the term is sufficiently clear to avoid such art. See specifically Amgen v. Chugai, 927 F.2d 1200 (Fed. Cir. 1991), where the court found the recitation of a specific activity of “about” 160,000 indefinite since it gave no hint as to which value between the prior art value of 128,620 and 160,000 constituted infringement. As noted at page 1218 of the decision, the holding was further supported by the fact that “nothing in the specification, prosecution history, or prior art provides any indication as to what range of specific activity is covered by the term”.

In this case, nothing in the instant specification, prosecution history, or prior art provides any indication as to what values would be covered by the claimed term “about”, as used in connection with the term “water activity”. Moreover, close prior art (US 2005/0147719 A1 and USP 5,000,973: see the “Anticipation” section infra) exists which is seen to fairly invoke a finding of indefiniteness under the reasoning of the Chugai holding.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-3, 8, 11-14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill et al (US 2005/0147719 A1).

The prior art discloses rawhide chews ("dentifrices" since they are used for cleaning teeth) impregnated with emulsified surfactants (such emulsions being a type of "dental cream" as required by instant claim 13: see paragraph [0190] and paragraphs [0198] – [0224]) or toothpaste ingredients including sodium fluoride and abrasives ((paragraphs [0233] – [0238]); the toothpaste being formed *in situ* by chewing action (paragraph [0242])). Working example 1 (paragraph [0254]) discloses compositions containing 1 percent tetrasodium pyrophosphate (a tetra-alkali metal pyrophosphate as preferred by Applicant and recited by instant claim 14) and 1 percent sodium bicarbonate.

Art Unit: 1614

The prior art compositions, once dried, have a water content of less than 13 percent and a water activity below about 0.75 (paragraph [0127]). The latter value of “about 0.75” is viewed as overlapping the value of less than “about 0.60” as recited by instant claim 1, since no clear line of demarcation exists with regard thereto due to the lack of guidance from the specification on the extent of variation permitted in the relative term “about”, as discussed in the “Indefiniteness” rejection supra).

2) Claims 1-3, 5, 11, 14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Scaglione et al (USP 5,000,973).

The prior art discloses dog biscuits comprising 0.1 to 10 weight percent inorganic pyrophosphate (col. 8, lines 22-24), preferably an alkali metal pyrophosphate such as tetrasodium pyrophosphate (a tetra-alkali metal pyrophosphate as preferred by Applicant and recited by instant claim 14: see col. 10, lines 61-64), and surfactants: col. 13, lines 19 and 20. Table 4 at col. 24 discloses compositions containing both tetrasodium pyrophosphate and sodium bicarbonate, the latter in amounts ranging from 0.374 to 27 percent by weight.

The prior art compositions, once dried, have a water content of less than 13 percent (col. 7, lines 57-59) and a water activity of 0.70 or less (col. 14, lines 35-37). The latter value of “0.70” is viewed as overlapping the value of less than “about 0.60” as recited by instant claim 1, since no clear line of demarcation exists with regard thereto due to the lack of guidance from the specification on the extent of variation permitted in the relative term “about”, as discussed in the “Indefiniteness” rejection supra).

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-3, 8, 11-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al (US 2005/0147719 A1).

The prior art is discussed in subsection “1)” of the “Anticipation” rejection supra. It will be presumed, in the interest of completeness prosecution, purely *arguendo* and for the purposes of this ground of rejection only, that the prior art value of “about 0.75” does not anticipate the instantly claimed value of less than “about 0.60”.

Accordingly, for the purpose of this rejection the presumption will be made that the prior art differs from the instant claims insofar as it does not expressly disclose a water activity of less than “about 0.60”, although it clearly suggests a water activity “below” about 0.75 at paragraph [0127].

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). Similarly, the determination of optimal values within a disclosed range is generally considered obvious. In re Boesch, 205 USPQ 215 (CCPA 1980). Accordingly, it would have been obvious to have prepared dog chews having lower water activities (about 0.60 or less) where same would have provided workable/optimal performance, given the open-ended suggestion to use sizes “below” about 0.75 by the prior art, and consonant with the reasoning of the cited case law.

2) Claims 1-3, 5, 11, 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scaglione et al (USP 5,000,973).

The prior art is discussed in subsection “2)” of the “Anticipation” rejection supra. It will be presumed, in the interest of completeness prosecution, purely *arguendo* and for the purposes of this ground of rejection only, that the prior art value of “0.70” does not anticipate the instantly claimed value of less than “about 0.60”.

Accordingly, for the purpose of this rejection the presumption will be made that the prior art differs from the instant claims insofar as it does not expressly disclose a water activity of less than “about 0.60”, although it clearly suggests a water activity and a water activity of 0.70 “or less” at col. 14, lines 35-37.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). Similarly, the determination of optimal values within a disclosed range is generally considered obvious. In re Boesch, 205 USPQ 215 (CCPA 1980). Accordingly, it would have been obvious to have prepared dog biscuits having lower water activities (about 0.60 or less) where same would have provided workable/optimal performance, given the open-ended suggestion to use activities “less than 0.70” by the prior art, and consonant with the reasoning of the cited case law.

Allowable Subject Matter

Claims 4, 6, 7, 9, 10, 15 and 18-22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and/or second paragraphs as set forth in this Office action, and to include all of the limitations of the base claim and any intervening claims.

The prior art of record does not fairly suggest, teach or disclose the specific two phase calcium/orthophosphate dentifrices recited by instant claims 4, 15, 18, 20 and 22. (These are special types of dentifrices for accelerating remineralization in humans, and thus would not be suggested by prior art relating to dog chews and biscuits).

The prior art of record also does not fairly suggest, teach or disclose dentifrices containing humectants in amounts of at least 10 percent by weight as recited by instant claims 6, 7, 9, 10, 19 and 20. (The use of a humectant, i.e., an agent which promotes softening or inhibits hardening, would be inapposite for prior art concerned with producing hard products such as dog chews and biscuits).

The use of humectants is generally associated with dentifrices such as toothpastes, creams and gels. And, as shown in instant specification, the use of the instantly claimed water activities in such dentifrices containing sodium bicarbonate and specific anionic components such as pyrophosphates unexpectedly reduces undesirable crystal formation. See specifically working example 1 (p. 15 of specification). These showings are thus sufficient to rebut any case of obviousness

Art Unit: 1614

which might, *arguendo*, be established over USP 5,318,773 (cited on Applicant's Form 1449) which is viewed as the closest prior art of record pertaining to toothpastes, creams and gels. Note that all the working examples therein use excess water to glycerin, and thus do not fairly suggest, teach or disclose the instantly claimed water activities, nor the unexpected reduction in crystal formation observed therewith. (The examiner further believes that no *prima facie* case exists as well, since USP 5,318,773 does not provide any direction for selecting any particular water activity, which is a function of many complex factors, each of which must be judiciously selected and balanced as described at the first paragraph of p. 10 of the instant specification).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1614

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Fred Krass", written in a cursive style.